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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/077,718 06/08/98 NYQVIST H 1103326-0503

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WHITE & CASE LLP
PATENT DEPARTMENT
1155 AVENUE OF THE AMERICAS
NEW YORK NY 10036

EXAMINER

SOLOLA, T	
ART UNIT	PAPER NUMBER

1626
DATE MAILED:

11/02/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/077,718

Applicant(s)

Nyqvist et al.

Examiner

Taofiq A. Solola

Art Unit

1626



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jul 23, 2001
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3-5, 12-18, and 20-22 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3-5, 12-18, and 20-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 27
- 18) ☐ Interview Summary (PTO-413) Paper No(s).
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

Art Unit: 1626

Therefore, claims 3-5, 12-18, 20-22, are pending in this application.

Claims 1-2, 6-11, 19, are canceled.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 3-5, 12-15 and 20-21, are rejected under 35 U.S.C. 103(a) as being unpatentable over Evenden et al., WO 95/11891.

Applicants claim tartaric salts of (R)-3-N,N-dicyclobutylamino-8-fluoro-3,4-dihydro-2H-1-benzopyran-5-carboxamide, their composition and method of use for the treatment of CNS disorders. Evenden et al., teach similar compounds having general formula I (page 5, lines 1-20); their organic and inorganic acids salt including salts of hydrochloric and tartaric acids (page 7, line 7), their pharmaceutical preparations (compositions) and method of use for the treatment of CNS disorders. See the abstract, page 11, lines 1-11. The difference between the instant invention and that of Evenden et al., is in the generic descriptions of the claimed compounds (salts). Therefore, the instantly claimed invention is prima facie obvious from the teaching of Evenden et al., because the indiscriminate selection of "some" among "many" is prima facie

Art Unit: 1626

obvious. In re Lemin, 141 USPQ 814. The motivation to make the claimed compounds is to make additional compounds useful for treating CNS disorders.

Claims 16-18 and 22, are rejected under 35 U.S.C. 103(a) as being unpatentable over Evenden et al., WO 95/11891.

Applicants claim a process of making tartaric salts of (R)-3-N,N-dicyclobutylamino-8-fluoro-3,4-dihydro-2H-1-benzopyran-5-carboxamide comprising dissolving (R)-3-N,N-dicyclobutylamino-8-fluoro-3,4-dihydro-2H-1-benzopyran-5-carboxamide in an aqueous or non-aqueous organic solution of tartaric acid. Evenden et al., teach similar compounds having general formula I (page 5, lines 1-20), and a process of making their salts comprising adding ether solution of the compounds to a second ether solution of hydrochloric acid. Evenden et al., also teach that tartaric acid could be used to make the salts (page 7, line 7). The difference between the instant invention and that of Evenden et al., is in the generic descriptions of the claimed compounds (salts). Therefore, the instant invention is prima facie obvious from the teaching of Evenden et al., because the indiscriminate selection of "some" among "many" is prima facie obvious. In re Lemin, 141 USPQ 814. The motivation is to make additional salts useful for treating CNS disorders.

Applicants' arguments filed 7/23/01 have been fully considered during the interview with Applicants' attorney on 10/12/01. See Interview Summary, Paper No. 26.

Art Unit: 1626

This is a RCE of applicants' earlier Application No. 09/077,718. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

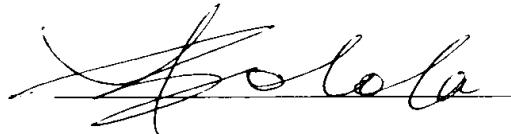
Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Taofiq A. Solola whose telephone number is (703) 308-4690. The examiner is on flexible work schedule and is generally out of the office on Wednesdays.

Art Unit: 1626

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph McKane, can be reached on (703) 308-4537. The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

A handwritten signature in black ink, appearing to read 'Taofiq A. Solola', written over a horizontal line.

Taofiq A. Solola, Ph.D.

Primary Examiner

Group 1626

November 1, 2001